Spring 2004

GATHERING FRIENDS

THE NEWSLETTER OF FRIENDS RESEARCH INSTITUTE

FRI Investigator

CONDUCTS INNOVATIVE RESEARCH IN THE *Republic of South Africa (RSA)*

Donnie W. Watson, Ph.D., FRI Principal Investigator, is making strides in the effort to reduce drug abuse and addiction in South Africa. The National Institutes of Health (NIH) and the National Institute of Drug Abuse (NIDA) funded this preliminary work to evaluate the feasibility of implementing training and treatment strategies in the Republic of South Africa (RSA). In this regard, Drs. Watson, Rawson and Rataemane are examining methods to introduce training and the subsequent use of manualized substance abuse treatment in the region. The goal is not only to reduce substance abuse and addiction, but also to examine how formalized treatment approaches impact adverse behavioral, social and health consequences that often accompany it (e.g., HIV/AIDS).

The manualized treatment approach used in this endeavor is the Matrix Model on Addiction Treatment. The Matrix Model incorporates multiple science-based components that have been shown to be effective in the treatment of substance abuse (e.g., cognitive behavioral techniques, motivational interviewing). Combining these treatments into a standardized manual allows the system to be easily taught to clinicians. An additional benefit of the approach is its adaptability for use with different cultures and populations.

Dr. Watson with a child of the RSA.

In order to accomplish project goals, the first phase of the endeavor in South Africa occurred last spring. Dr. Rataemane, the study's South African collaborator, provided Drs. Watson and Rawson an overview and tour of various clinics in South Africa. They met with clinicians and clinic directors to discuss their existing substance abuse therapies. Subsequent to these meetings, Drs. Watson and Rawson made formal presentations on the Matrix Model. Interactions with clinicians and clinic directors indicated uniform endorsement of the plan to learn and implement the Matrix Model. Thus, the model was deemed a viable and culturally appropriate approach for use in South Africa.

Continued on page 2

WHAT'S INSIDE:

Republic of South Africa

continued from page 1

Dr. Watson giving a presentation on the Matrix Model to clinicians in the RSA.

The next step of this project is to train South African clinicians in the Matrix Model. This training is slated to take place in Los Angeles in the spring of 2004. A group of senior clinicians from RSA will participate in the training and then return to implement the model in their respective community treatment centers. It is hoped that the results of this "open trial" may provide the researchers with pilot data that will be used to generate R01 applications to further this work.

Gathering Friends *is a publication of Friends Research Institute, Inc. (FRI). Please forward any correspondence to Julie Simon Agetstein, FRI, 505 Baltimore Avenue, P.O. Box 10676, Baltimore, MD 21285.*

Editorial Staff: Julie Simon Agetstein and Beverly Rosen

Contributors: Amber Hollingsworth and Ned Rubin

FRI Launches New Website

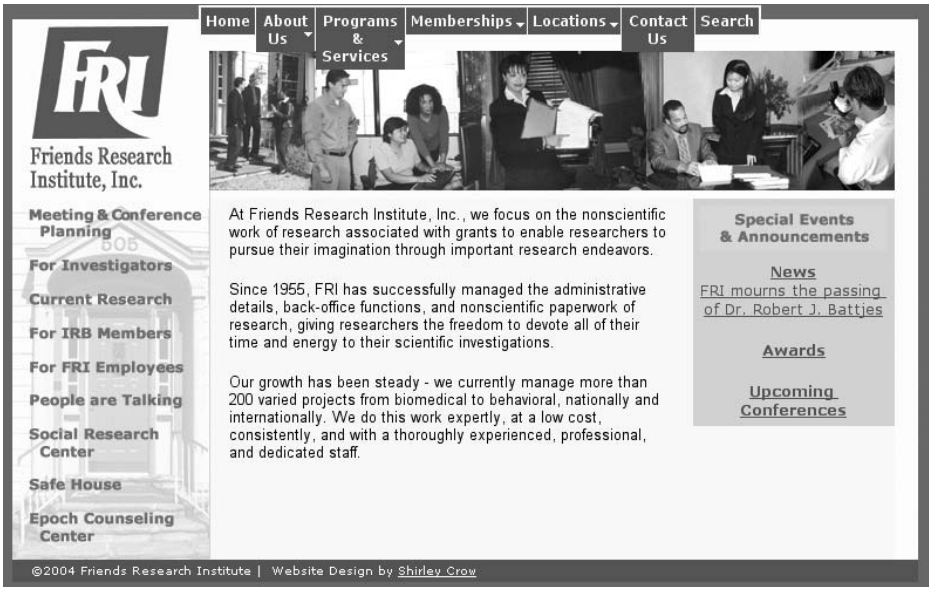
FRI's new website www.friendsresearch.org was recently launched, and the response and feedback have been very encouraging. Our newsletter readers who visited the old site will find tremendous improvements, richer and more comprehensive information, and easy navigation.

For those of you who might be new to the site, we encourage you to visit it often, as updates and new information will appear regularly.

Some features of the website include:

- Special sections for Investigators and for IRB members containing material that they need in an easy-to-access format;
- An interesting narrative of how the organization started and grew;
- Details about upcoming conferences and online registration;
- Complete listings of current research along with a map showing the research sites, which are updated regularly;
- A form whereby FRI supporters can make a donation to the organization;
- Photographs of the current staff, to enable you to "put a face to the name";
- A search feature for visitors to find a specific area of interest;
- Information regarding FRI's awards, their criteria, deadlines and details, as well as information about past winners;
- Current issues of the FRI Newsletter.

FRI encourages you to visit the site often, and we welcome your constructive suggestions. Please submit your feedback to Michele Hipsley at mhipsley@friendsresearch.org.



Congratulations on Your Retirement

After 24-1/2 years of service to Friends Research Institute as the East Coast Grants Administrator, Eleanor Bruns retired at the end of April of this year. Throughout her years at FRI, Ms. Bruns has been a very dedicated and loyal employee. Although she will be sorely missed, FRI wishes her a very long and happy retirement.

Ask The IRB Staff

What should be included in the informed consent document?

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate. The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. Part A states that the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements shall also be provided to each subject, in accordance with 45 CFR 46.116(b):

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

Additionally, the Food and Drug Administration's (FDA) regulations require that informed consent documents note the possibility that the FDA may inspect the study records. The FDA also explicitly requires that consent forms be dated as well as signed by the subject or the subject's representative.

Informed consent documents should be written in language that is understandable to the subject or the representative. They may not include exculpatory language through which the subject or the representative is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. Finally, use of the first person is not recommended (e.g., "I understand that…") as it can be interpreted as suggestive.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that certain conditions are met and documented under 45 CFR 46.116(c) or (d). Furthermore, the IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

For more information regarding informed consent for specific research, please contact the IRB staff, Julie Agetstein on the East Coast, and RoseAnn Fleming on the West Coast.

Quality Improvement

"The pursuit of quality is a never-ending, continuous process that must be owned by everyone in the organization."

Health care and research systems are incredibly complex, possibly the most complex of all human systems. Even the best run systems will eventually have a failure. Quality Improvement (QI) theory teaches that these "routine failures cannot be entirely avoided, but their impact may be lessened through quality interventions such as routine and special Quality Assurance audits to look for variations in quality, reports from employees of potential quality concerns, patient and participant complaints, and variations noted in "benchmarks." Benchmarks are predetermined operational standards assumed to represent measures of institutional quality. Some benchmarks that research organizations utilize are: on-site serious adverse event reports, sick time usage, employee injuries, number of "abandoned" telephone calls ("hang-ups" before answer), seminar and internal workshop attendance, OHRP Letters of Determination, privacy complaints, IRB meeting attendance, and timeliness of employee evaluations. If you think of any benchmarks, which you feel should be examined, please contact Ned Rubin, Director of QI and Compliance at (904) 493-6125, or via email at nrubin@friendsresearch.org.

As a reminder, the Potential Quality Issue (PQI) form can be accessed on FRI's newly enhanced website, under the "Programs and Services" section, then under, "QI Program," at the bottom of the page. This form can be used to inform the QI department of possible barriers to optimum quality. Please note that all communications with the QI department are confidential. We welcome your PQIs and other suggestions.

CONGRATULATIONS!

FRI is happy to announce that Julie Simon Agetstein, East Coast Human Protections Coordinator, received her Certification in IRB Management after passing the CIM exam sponsored by the National Association of IRB Managers, Inc. She ranked second out of the 36 people who passed the exam. Congratulations to Julie on this achievement.

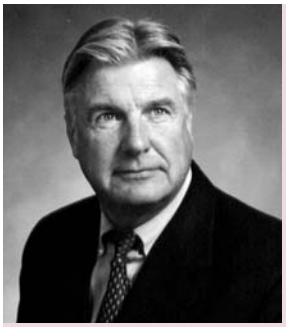
Three New Members Bring Exceptional Experience to FRI's Institutional Review Boards

FRI is pleased to announce the appointment of one new member to its West Coast IRB and two new members to its East Coast IRB, since February of 2004. All have exceptional experience and will provide even greater protection to FRI's human research participants.

Donnie Watson, Ph.D., FRI Principal Investigator (PI), joined the West Coast IRB in February. With a Ph.D. in Clinical Psychology and over twenty years of experience in substance abuse with adults and minors, Dr. Watson brings expertise on these issues, and a unique perspective as a researcher to the IRB. To prevent the appearance of a possible conflict of interest, Dr. Watson leaves the meeting when his protocols are being reviewed.

At the May IRB meeting two new members will begin their tenure with the East Coast IRB. *Caroline Burry, Ph.D., LCSW–C*, an Associate Professor in the School of Social Work of the University of Maryland Baltimore and an expert in child welfare, will become another children's advocate for the IRB. Additionally, *Rev. LaVern Murray* will replace Rev. Highfield (who will attend his last meeting in May after 14 years of exceptional service) as the Community Member. She is a Reverend for the Doxa Ministries and runs the spirituality groups for the Center of Addiction and Pregnancy at Johns Hopkins Bayview Medical Center.

The new IRB members will bring fresh insight, enthusiasm, expertise, and sensitivity to FRI's IRBs, and we look forward to their continued dedication and service. FRI appreciates all of its IRB members who help to advance science and research at FRI, while protecting the very people that make research possible.



A Message from the Executive Director

It is with deep sadness that I inform you of the death of one of FRI's most beloved colleagues. Dr. Robert J. Battjes passed away on March 30 after a sudden illness. Bob had served as Director of FRI's Social Research Center from 1999 until his death.

Part of Bob's legacy is that he made education and mentoring new investigators an organizational value. Many of the young investigators at FRI feel a sense of personal loss for a man who encouraged them and rewarded their contributions by citing them as co-authors on his published work. Many became first authors on articles for peer-reviewed journals thanks to Bob's editing of their work.

He is also remembered by those with whom he worked as a fair and kind professional. Bob was a dedicated researcher who cultivated an outstanding research team for FRI. Robert P. Schwartz, M.D., FRI's Medical Director, reflected on Bob as "a kind and generous man who cared deeply about people. He was a superb scientist whose work was driven by a passion to improve the lives of people with drug addiction and AIDS. We will all miss his advice, his friendship, and his laughter."

Barry Brown, Ph.D., FRI Principal Investigator, considered Bob to be instrumental to their field. "He uniquely combined extraordinary organizational skills with a deep and abiding concern for the human condition. Those qualities, together with his considerable intellect and a soft-spoken but unmistakable tenacity of purpose, led to his making contribution to science and practice in such diverse areas as drug abuse prevention, HIV epidemiology and, of course, drug abuse treatment. He'll be missed as both mentor and friend by those of us fortunate enough to have known and worked with him."

Prior to joining SRC, Bob held several executive positions at the Division of Clinical and Services Research at the National Institute on Drug Abuse in Rockville, MD including Acting Director, Deputy Director, and Associate Director for Planning.

Bob's professional achievements were outstanding. He was recognized with a series of honors including the NIDA Director's Award of Merit and several awards from the Public Health Service: the Distinguished Service Medal, the Meritorious Service Medal, the Outstanding Service Medal, and the Commendation Medal.

During his professional career, Bob authored more than 40 peer-reviewed publications. His recent research interests focused on methadone maintenance treatment, and he served as Principal Investigator for a study evaluating the effectiveness of methadone maintenance treatment for heroin-addicted probationers. He was also PI or co-investigator for a number of additional supported research projects.

FRI extends its condolences to Bob's family and our staff. We will remember him always in our minds and hearts as a valued colleague and trusted friend.

Patrick F. Bogan

Employees' Corner

As you know by now, FRI's website has been completely modernized, and there is now a special section dedicated to FRI employees. This section includes our East Coast and West Coast handbooks as well as other policies that are used frequently, such as the sick bank policy and the education reimbursement policy. We also have our standard forms posted, all of which can now be completed online for your convenience.

A noteworthy segment of this section is "Employee News." This is the "fun" portion of the website and is a great way to catch up on what's happening with other employees in the organization. We invite all employees to utilize this section to announce engagements, weddings, births, retirements, achievements, promotions, etc. We currently have several announcements listed and encourage all employees to send in relevant information and to visit this section on a regular basis for the latest news.

Please email your information (and pictures, when available) to Michele Hipsley at mhipsley@friendsresearch.org.

Friends Research Institute, Inc.

505 Baltimore Avenue
P. O. Box 10676
Baltimore, Maryland 21285

410-823-5116
410-823-5131 fax

Happy Anniversary!

Congratulations to this quarter's employees who have celebrated an anniversary with FRI. We appreciate your loyalty and dedication to the organization.

JANUARY	YEARS
Jan Marshall	18
Dorothea Collins, Sc.D.	6
Robert Schwartz, M.D.	4
Elizabeth Katz, Ph.D.	4
Cynthia Adams	4
Judith Novgrod	3
Jeannette Taylor	3
Brenda Patterson	3
Alice Davis	3
Lynne Johnson	2
Pedro Mercado	2

FEBRUARY	YEARS
Judith Horst	14
Steven Shoptaw, Ph.D.	12
Christopher Hough, Ph.D.	8
Claudia Reynolds	6
Edward Sanders	5
Ruslan Damadzic, M.D.	5
Donnie Watson, Ph.D.	3
Linda Dickens	2
Ma Anna Teresa Mapa	2
Raymond Szczepanski	2
Marjorie O'Brien	1
Karen Dellert	1

MARCH	YEARS
Gail Needer	16
Steven Carswell	7
Donna Lucker	6
Tiffany Terry	5
Leslie Amass, Ph.D.	4
Jonathon Kamien, Ph.D.	4
Anna Soisson	4
Susan Tangires	4
Ned Rubin	3
Fatima Paen	2
Etsegenet Meshesha	2
Julie Agetstein	2
Donna Beckman	1